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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,208	ISHIDA ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/24/2009, 9/4/2008, 8/12/2008 and 5/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Claims 4-7 and 11-13 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims 3 and 10. See MPEP § 608.01(n). Accordingly, the claims 4-7 and 11-13 not been further treated on the merits.

Regarding claims 4 and 11, they depend respectively on claims 3 and 10 which are multiple dependent claims. A claim can not depend on a multiple dependent claim. For purpose of examination, examiner treats claim 4 as if it was depended on claim 1 and claim 11 on claim 8.

Regarding claims 5-7 and 12-13, they are rejected because they depend on claims respectively on claims 4 and 11.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-2, 4 and 8, they are rejected because they include “and/or” which is unclear and indefinite. Applicant needs to precisely identify the claimed limitation. The phrase "and/or" renders the claim indefinite because it is unclear

whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 3, 5-7, 9-13, they are rejected because they depend on claims that are rejected for same reason above. Appropriate correction is required.

4. Claims 2 and 4 provide for the use of living body light, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 2 and 4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4-8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bukshpan (US Pat: 2002/0138003) in view of Tachibana et al (US Pat: 6,176,842).

Regarding independent claim 1, Bukshpan teaches a method for diagnosing and treating a thrombus that is pertinent to the claimed invention. Bukshpan teaches that the method includes introducing an ultrasound contrast agent into a human body, transmitting an ultrasound signal into the human body that is pertinent to the claimed invention. There is further provided a method for lysing a thrombus in a human body, including introducing an ultrasound contrast agent into the human body, transmitting an ultrasound signal towards the thrombus at least one transmission frequency, receiving an ultrasound signal reflected off of the thrombus, the received ultrasound signal having a temporal characteristic, calculating a spatial location of the thrombus from the temporal characteristic, and transmitting ultrasound energy towards the spatial location [see 0021]. Bukshpan teaches a method and apparatus for achieving ultrasonic coronary thrombolysis.

Bukshpan teaches an apparatus for treating a thrombus in a human body, including a sheet of material, the sheet being placeable on the human body, a plurality of ultrasound transmitters for transmitting ultrasound signals into the human body, the transmitters being fixedly located within the sheet, and the transmitters being oriented within the sheet such that the transmission is effected into the human body, a plurality of ultrasound receivers for receiving ultrasound signals reflected from the human body, the receivers being fixedly located within the sheet, and the receivers being oriented

within the sheet such that the reception is effected from the human body, a layer of ultrasound coupling medium applied to a surface of the ultrasound transmitters and the ultrasound receivers, the layer being conformable to a contour of the human body, and a processor for processing the received signals, the processor being functional to calculate a temporal characteristic of the received signals, and diagnose a thrombus from the calculated temporal characteristic [see 0021].

Bukshpan doesn't teach light source to irradiate the living body and light receiving unit.

However, Tachibana et al teaches delivery ultrasonic energy to a light activated drug, contrast agent or thrombolytic agent that is injected to a patient for therapeutic purposes such as treating thrombosis [see column 10 lines 56-58]. Tachibana et al also teaches transmitting ultrasound waves or energy to penetrate the tissue site for [see abstract]. A light source, such as a fiber optic, is then directed to a targeted tissue site which includes the light activated drug. The tissues of the tissue site are then exposed to light from the light source in order to activate any light activated drugs within the tissue site [see column 1 lines 42-54]. Tachibana et al teaches other suitable therapeutics includes, but is not limited to: thrombolytic agents such as urokinase; coagulants such as thrombin [see column 10 lines 56-58]. Example describes the delivery of a light activated drug to a thrombosis.

Therefore, one with ordinary skill in the art would have been motivated to use the processor to process the output signal of the light from the body to detect a thrombus passing through a blood vessel; for the purpose of achieving dissolution of the

thrombus as soon as possible after the onset of the symptoms in order to reestablish adequate blood flow to the myocardium. One with ordinary skill in the art at the time the invention was made would have been motivated to use the light detection unit; in order to detect the backscattered light from the region of interest for further analysis and/or evaluation.

Regarding independent claim 8, all other limitations are taught as set forth by the above combination.

Bukshpan further teaches methods for ultrasonic diagnosis and localization of vascular thrombi employ standard ultrasonic imaging techniques, whereby the amplitudes (Amplitude is directly related to the *acoustic energy* or intensity of a sound) of reflected ultrasound waves are analyzed so as to construct an image of the thrombus. In terms of standard ultrasound imaging techniques, therefore, only objects which produce reflected ultrasound signals of sufficiently high amplitude as to allow the signals to be individually detected by the receiving ultrasound crystal can be imaged [see 0009]. According to this paragraph Bukshpan detects thrombus with high intensity of measured or reflected ultrasound waves. Detection of thrombus is accomplished the high intensity range and higher for thrombolysis which is dissolution of thrombi.

Bukshpan teaches administration of the ultrasound by means of an intravascular ultrasound (IVUS) transducer. In this technique, a small ultrasound transducer located on the tip of a coronary artery catheter is advanced through the coronary circulation and positioned on the thrombus. Ultrasound energy is then administered directly onto

the clot, allowing a sufficient intensity of ultrasound energy to be achieved in the thrombus as to cause disruption of the blood clot [see 0011]. As the catheter in the artery moves along with the pulsations of the myocardium, unnecessary exposure of surrounding tissue to damaging ultrasound energy is minimized [see 0011]

Regarding claims 4-5, and 11-13, all other limitations are taught as set forth by the above combination. Bukshpan teaches a sheet that can be held in place on the patient's body by straps. Several units of transducer pad may be connected to each other in series for use on a patient with a larger chest wall; and are connected to a computer processor in control unit which includes a display [see 0035]. The computer processor can be used as light measuring apparatus to display a state of blood stream. A thrombus-specific ultrasound contrast agent (MRX-408) is injected intravenously into the patient by the operator. The operator then initiates operation of device by means of control unit. The device first performs a process of thrombus detection (the diagnostic phase) [see 0037].

The above combination doesn't displaying a state of blood stream.

However, Bukshpan further teaches methods for ultrasonic diagnosis and localization of vascular thrombi employ standard ultrasonic imaging techniques, whereby the amplitudes of reflected ultrasound waves are analyzed so as to construct an image of the thrombus [see 0009].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to use the computer processor and the display as taught

by Bukshpan to construct and image of the thrombus and to display a state of the blood stream; in order to accurately evaluate the severity of clotting of the blood vessel with an increase visualization for the purpose of prescribing the best possible treatment.

Regarding claims 6-7, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach adjusting and control the injection amount and the irradiation time.

However, Bukshpan teaches an operator can initiate operation of device by means of control unit [see 0037]; and an output on monitor indicates to the operator of device that a thrombosis has been detected. In this event, the operator administers an intravenous thrombolytic agent (such as tPA) and then manually initiates a process (typically by pressing a button) of clot localization and immediate lysis by device 20. In an alternative embodiment, the intravenous thrombolytic agent may be bound to a thrombus-specific ultrasound contrast agent. Bukshpan further discusses treatment time up to 90 minutes and the danger of irradiating the regions with a long period of time [see 0012-13].

Bukshpan discloses that current techniques for achieving ultrasound thrombolysis of coronary blood clots are thus either laborious (requiring the performance of formal cardiac catheterization in a laboratory), time-consuming (requiring at least 30 minutes of ultrasound exposure) or dangerous (due to excessive

exposure of healthy tissue to damaging, unfocused, ultrasound energy). Thus, despite the efficacy of ultrasound as a modality for achieving thrombolysis, no currently known technique of ultrasound administration is clinically useful in the early treatment of coronary thrombosis [see 0014].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the Bukshpan reference by allowing the operator to adjust and control the irradiation time; in order to minimizing the possibility of damaging surrounding tissues.

7. Claims 2-3 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bukshpan (US Pat: 2002/0138003) in view of Tachibana et al (US Pat: 6,176,842) as applied to claims 1 and 8 above, and further in view of Zacouto (US Pat: 5,305,745).

Regarding claims 2-3 and 9-10, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach an alarm device to generate an alarm based on a detection result; and a portable self power source.

However, Zacouto teaches detected images can be of blood corpuscles or cells which are abnormal in shape, content, localization or number, and on the other hand, transmitted to the exterior upon request by radio frequency transmission. The device can also trigger, for example, an external alarm by means of radio frequency to signal the observation of an abnormal image. It can also trigger automatic delivery of doses of a suitable drug, when the doses are programmed for this purpose [see column 6

lines 40-49]. The device can also allow automatic telecommunication with emission of a selective alarm or of measured biological data, according to known methods [see column 14 lines 12-15]; when there is a decrease of the myocardial impedance, the device triggers an external alarm and/or an automatic perfusion of thrombolytics or other drugs [see column 23 lines 20-25].

Zacouto also teaches a portable electrical stimulator preferably implanted but could be external, external energy source that can be worn on the belt [see column 19 lines 39-44]

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by incorporating an alarm device and generate an alarm when a result is detected; for the purpose of alerting the operator to alter delivery of ultrasonic energy or waves, In order to monitor/control exposure time.

One with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by using a portable self power source; in order to have the capability of invasively treating or diagnose thrombus; thereby eliminating the need of cumbersome electrical cables.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is

(571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768